

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF TEXAS  
FORT WORTH DIVISION

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JAMES SHEPHERD, Trustee for the JAMES B.  
SHEPHERD TRUST, et al.,

Plaintiffs,

v.

ENVIRONMENTAL PROTECTION AGENCY,  
et al.,

Defendants.

Civil Action No. 4:23-CV-826-P

**DEFENDANTS' MEMORANDUM IN SUPPORT OF RESPONSE IN OPPOSITION TO**  
**PLAINTIFFS' AMENDED MOTION FOR PRELIMINARY INJUNCTION**

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## Introduction

This case is about the United States Environmental Protection Agency’s authority to take enforcement action against the unlawful sale of unregistered pesticide products regulated by the Federal Insecticide Fungicide and Rodenticide Act (“FIFRA”). EPA is authorized to issue unilateral orders called Stop, Sale, Use, or Removal Orders (“SSUROs”) whenever it has reason to believe that a pesticide has been or is intended to be distributed or sold in violation of any provision of FIFRA. 7 U.S.C. § 136k(a). When EPA learned that Berkey water filtration products (“Berkey products”) incorporated anti-microbial silver and were being sold in multiple states with claims that they could remove more than 99.999% of viruses and 100% of pathogens from water sources, the agency had the requisite reason to believe that the sale and distribution of Berkey products violated FIFRA. EPA therefore used its authority to issue SSUROs to seven Berkey product sellers.

The entities subject to those orders are not parties in this lawsuit. Nor have they sought judicial review of those orders in another action. Instead, Plaintiffs—entities that license and, in NMCL’s case, distribute Berkey products—challenge the orders issued to others who manufacture components for, or distribute and sell, Berkey products. They now seek a preliminary injunction prohibiting EPA’s enforcement of orders issued to third parties.

Plaintiffs’ motion for emergency relief fails. They cannot show a likelihood of success on the merits because they lack third-party standing, and because their claims, even if justiciable, are meritless. They do not demonstrate irreparable harm both because they have not shown how they, as opposed to various third parties, have been harmed by EPA’s orders, and because any conclusory allegations of economic harm are attributable to other factors, including a widely publicized class-action lawsuit alleging that Berkey products do not perform as advertised.

Finally, Plaintiffs cannot show that the public interest or balance of the equities tilts in their favor because they have no legally cognizable interest in their manufacturers or distributors evading the law, and because the public interest in regulating pesticide consumer products predominates. Plaintiffs thus fail to meet any element of the test that courts use to evaluate entitlement to emergency injunctive relief. *See Winter v. NRDC*, 555 U.S. 7 (2008). The Court should deny their motion.

### **Background**

#### **A. Parties and Nonparties**

Plaintiffs' claims center on the Berkey products, which includes Berkey water filtration systems and Berkey filter elements used in those filtration systems. Am. Compl. ¶ 28; Am. Mot. ¶ 200.<sup>1</sup> Plaintiffs are James B. Shepherd, Trustee for the James B. Shepherd Trust, who developed the Berkey system; the James B. Shepherd Trust ("JBS Trust"); and New Millennium Concepts, Ltd ("NMCL"). Am. Compl. ¶¶ 1-3, 28-30. Berkey International, LLC ("Berkey International"), which manufactures Berkey systems, is not a Plaintiff. Am. Compl. ¶ 29.

According to the allegations of the Amended Complaint, these entities have a complicated relationship. The JBS Trust holds "equitable title to the majority partnership interest in" NMCL and "legal title to intellectual property licensed to NMCL," and licenses NMCL and others "to manufacture and sell Berkey water filtration products." Am. Compl. ¶ 1.<sup>2</sup> The JBS Trust "receives royalties on the gross sales of Berkey filters sold by NMCL and Berkey International, LLC." *Id.*

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<sup>1</sup> To differentiate between Plaintiffs' Amended Motion for emergency relief and their Amended Complaint, EPA cites paragraphs contained in Plaintiffs' Amended Motion as "Am. Mot. ¶ [ ]" and paragraphs in their Amended Complaint as "Am. Compl. ¶ [ ]."

<sup>2</sup> Confusingly, the Amended Complaint later alleges that NMCL "has an *exclusive* license from the JBS Trust to market Berkey Water Filtration products." Am. Compl. ¶ 30.

The Amended Complaint also alleges NMCL is a distributor for Berkey International, *id*, and that NMCL “pays royalties based on gross sales for Berkey filter products.” Am. Compl. ¶ 2. There are at least two manufacturers who hold a license to construct Berkey products: Berkey International and “Vendor B.”<sup>3</sup> Am. Compl. ¶ 29; Am. Mot. ¶ 199. Neither Berkey International nor Vendor B are parties here. Yet the Amended Complaint states that it “may jointly refer to the JBS Trust, NMCL, and Berkey Int’l corporately as ‘Berkey.’” Am. Compl. ¶ 30. In this opposition brief, the term “Plaintiffs” refers to James B. Shepherd, the JBS Trust, and NMCL only.

The Plaintiffs allege damages from SSUROs issued to Berkey International and other third-party entities who distribute, sell, or package Berkey products. The third-party SSURO recipients are identified below.

## B. Legal Background

### 1. FIFRA’s registration requirement

The Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA” or “the Act”), 7 U.S.C. §§ 136-136y, governs the production, sale, distribution, and use of pesticides. FIFRA’s principal purpose is to protect human health and the environment from unreasonable adverse effects associated with pesticides. *See Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991-92 (1984). The Act makes it unlawful, with some exceptions, for any “person in any State [to] distribute or sell to any person any pesticide that is not registered” under the Act. 7 U.S.C. § 136a(a); *see also id.* § 136j(a)(1)(A). A registration granted by EPA under FIFRA is a license that establishes the terms

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<sup>3</sup> The Amended Complaint and Amended Motion for Preliminary Injunction identify Berkey International as one of the manufacturers of Berkey products and refers to Berkey International as Vendor A. Am. Compl. ¶ 68. A second manufacturer of Berkey products is identified as Vendor B, and the identity of that entity is not disclosed in the Amended Complaint or Amended Motion for Preliminary Injunction. Am. Mot. ¶ 199.

and conditions under which the pesticide may be lawfully sold, distributed, and used. *See id.* §§ 136a(c)(1)(A)-(F), 136a(d)(1).

A “pesticide” includes “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u).<sup>4</sup> As more fully explained below, longstanding EPA regulations define when a “substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration.” 40 C.F.R. § 152.15.

EPA may not issue a registration for a pesticide use that would create “unreasonable adverse effects on the environment.” *See* 7 U.S.C. § 136a(c)(5) & (7). EPA registers a pesticide after conducting a scientific review of the risks and benefits of that pesticide. Prospective registrants must submit to EPA, as part of the application for registration, information on the risks associated with the use of the pesticide. *Id.* § 136a(c).

## **2. The distinction between “pesticides” and “devices” and its application to water filters**

EPA also regulates “devices” under FIFRA. A “device” is “any instrument or contrivance . . . which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life,” subject to certain exceptions not relevant here. 7 U.S.C. § 136(h). Device producers, like pesticide producers, must register “establishments” in which they produce their devices, *see id.* § 136e; 40 C.F.R. pt. 167, and they are subject to prohibitions on “[m]isbranding,” 7 U.S.C. § 136(q). But unlike pesticides, devices are not subject to FIFRA’s product-specific, pre-sale registration requirements.

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<sup>4</sup> An organism is a “pest” under FIFRA when it is “deleterious to man or the environment” and is “[a]ny fungus, bacterium, virus, prion, or other microorganism,” subject to exceptions not relevant here. 40 C.F.R. § 152.5(d).

Since 1975, EPA has interpreted “devices” to include “water filters . . . (except those containing substances or mixtures of substances which are pesticides).” Part 162—Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added). As EPA explained in a 1976 guidance document, if an “article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide.” Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976).

EPA’s longstanding view is reflected in more recent guidance available on the Agency’s website. Under the heading “Products Commonly Mistaken as Devices,” EPA notes that:

Where a product that would otherwise be a device also incorporates a pesticidal substance, it may be considered a pesticide product. For example, a filter that physically traps microbial pests (generally a device) would be an antimicrobial pesticide product if it also incorporated a pesticidal substance that kills those pests to improve the efficacy of the entire system.

U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides, (last updated Dec. 29, 2022).<sup>5</sup>

Similarly, EPA’s Pesticide Registration Manual explains that if “a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3.” U.S. EPA, *Pesticide Registration Manual: Chapter 13 - Devices*, Pesticide Registration, (last updated Mar. 1, 2023).<sup>6</sup> The Pesticide Registration Manual also notes that in “applying the definition of ‘device’ in FIFRA section 2(h), EPA examines each individual product on a case-by-case basis” and that a manufacturer “uncertain about whether [its]

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<sup>5</sup> Available at <https://www.epa.gov/pesticides/pesticide-devices-guide-consumers> (last visited Aug. 16, 2023)

<sup>6</sup> Available at <https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-13-devices> (last visited Aug. 16, 2023).

product requires EPA registration as a pesticide . . . may request a determination from EPA.” *Id.* The Manual provides that EPA will make those determinations within four months. *Id.*

### **3. The Treated Article Exemption and its limitations**

Products that are “treated with or contain[] a pesticide” may be exempt from otherwise applicable registration requirements if the pesticide with which they are treated is intended only “to protect” the articles or substances themselves, and only if that pesticide “is registered for such use.” 40 C.F.R. § 152.25. But under EPA’s longstanding interpretation, “articles or substances bearing implied or explicit public health claims against human pathogens” do not qualify for this exemption, known as the Treated Article Exemption. U.S. EPA, Pesticide Registration (PR) Notice 2000-1, Notice to Manufacturers, Formulators, Producers and Registrants of Pesticide Products (Mar. 6, 2000).<sup>7</sup> Public health claims include, *inter alia*, claims “for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals)”); claims “for the product as a sterilant, disinfectant, virucide or sanitizer, regardless of the site”; or “non-specific claim[s] that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.” *Id.* at 2-3.

### **4. EPA’s enforcement authority**

EPA “is charged with choosing the means by which to enforce and achieve the goals of FIFRA.” *Sultan Chemists, Inc. v. EPA*, 281 F.3d 73, 83 (3d Cir. 2002). One enforcement option available to EPA is the issuance of a SSURO. 7 U.S.C. § 136k(a). EPA may issue SSUROs “[w]henever any pesticide or device is found by the Administrator in any State and there is reason

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<sup>7</sup> Available at <https://www.epa.gov/pesticide-registration/prn-2000-1-applicability-treated-articles-exemption-antimicrobial-pesticides> (last visited August 16, 2023).

to believe . . . that such pesticide or device has been or is intended to be distributed or sold in violation of any” provision of FIFRA. *Id.* Once issued, a SSURO prohibits the sale, use, or removal of a pesticide, “except in accordance with the provisions of the order.” *Id.*

### C. Factual Background

#### 1. Silver regulation in the United States

The United States has regulated silver as an antimicrobial pesticide since 1954.<sup>8</sup> Ingestion of silver may cause lung and kidney lesions; breathing problems; lung and throat infections; abdominal pain; rashes, swelling, and inflammation on skin; and argyria<sup>9</sup> in humans and animals. *Id* at 2-4.

Currently, over 125 products containing silver are registered with EPA.<sup>10</sup> Among other uses, silver is registered under FIFRA to inhibit the growth of bacteria within the filter unit of water filter systems designed to remove objectionable taste, odors, and color from municipally treated tap water. *Id.*<sup>11</sup>

#### 2. Stop Sale, Use, or Removal Orders referenced in the Amended Complaint

In 2022, due to a statement posted on a third-party website, EPA learned that Berkey products contain antimicrobial silver and that Plaintiffs’ manufacturers and distributors claimed

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<sup>8</sup> U.S. EPA, [R.E.D. Facts Silver](#) at 2, June 1993, (last viewed on Aug. 29, 2023).

<sup>9</sup> Argyria causes human and animal skin to have a bluish, grey-blue, or black color. This change in skin color is typically permanent. *Id.*

<sup>10</sup> U.S. EPA, [Chemical Name: Silver](#), (last viewed on Aug. 29, 2023)

<sup>11</sup> See FIFRA registrations for water filters that contain silver include but are not limited to EPA: [Reg. No. 58295-3](#); [EPA Reg. No. 75456-1](#); [EPA Reg. No. 71332-5](#); and [EPA Reg. No. 35900-3](#), (last viewed on Aug. 29, 2023).

these products remove pests that threaten public health from water.<sup>12</sup> Am. Compl. ¶ 57; Am. Compl. Ex. B at 5-7; ECF No. 15 ¶ 8. Due to the silver in Berkey products and the pest removal claims, and the fact that the Berkey filter products were not registered with the EPA, EPA began investigating the products to determine whether they required registration under FIFRA. Am. Compl. Ex. B at 5-7. EPA's investigation confirmed that Berkey products contain silver; that Plaintiffs' manufacturers and distributors claim these products remove public health pests from water; that these products are not registered; and that Plaintiffs' distributors were selling these products throughout the United States. *Id.* EPA therefore issued SSUROs in accordance with EPA's authority under FIFRA and EPA's FIFRA Enforcement Response Policy.<sup>13</sup>

More specifically, EPA issued seven SSUROs to certain third-party distributors or manufacturers of Berkey products between December 2022 and May 2023.<sup>14</sup> Most commonly, these parties' advertisements claimed the products removed "99.999%" of "viruses" and "pathogenic bacteria (and surrogates)" from water.<sup>15</sup> However, their websites contained many other public health statements. Upon issuance of the SSURO, each recipient was required to stop the sale, use, and distribution of the offending products and, with respect to certain SSUROs, to

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<sup>12</sup> Plaintiffs make much of this being a third-party website. As discussed in the text, however, the SSUROs were based on information developed in EPA's subsequent investigation, which included a review of the recipients' own websites.

<sup>13</sup> 7 U.S.C. § 136k; U.S. EPA, *FIFRA Enforcement Response Policy*, December 2009, <https://www.epa.gov/sites/default/files/documents/fifra-erp1209.pdf> (last viewed on Aug. 29, 2023); Am. Compl. Ex. B at 13-22; 25-27; 30-37; 38-46; 47-53; 54-61; 62-69.

<sup>14</sup> The seven SSUROs issued by EPA are the six SSUROs listed in the table below and the SSURO issued to Vendor B. Amended Complaint Exhibit B contains copies of the six SSUROs listed in the table and the termination order related to the SSURO issued to Vendor B. Am. Compl. Ex. B at 13-22; 25-27; 30-37; 38-46; 47-53; 54-61; 62-69.

<sup>15</sup> Am. Compl. Ex. B at 13-22; 30-37; 38-46; 47-53; 54-61; 62-69.

provide EPA with an update on compliance with the SSURO every 30 days until the recipient no longer had any products that violated FIFRA in its inventory. The offending entities and products are detailed in the table below.<sup>16</sup> It is undisputed that the listed products contain silver and are not registered, and that none of the Plaintiffs received a SSURO.

<b>Stop, Sale, Use, or Removal Orders (“SSURO”)</b>			
<b>SSURO Recipient</b>	<b>Third-Party Type</b>	<b>Date Issued (on or about)</b>	<b>FIFRA Violative Products</b>
James Enterprises, Inc. DBA Berkey Filters  (Am. Compl. Ex. B at 13-22)	Distributor	Dec. 27, 2022	Black Berkey Filters Sport Berkey Replacement Filters, Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters, Berkey Light Water Filters Sport Berkey Water Bottles
Fritz Wellness, Professional Company DBA Fritz Wellness Center  (Am. Compl. Ex. B at 30-37)	Distributor	March 6, 2023	Black Berkey Filters Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters Crown Berkey Water Filters
Eden Valley Farms LLC  (Am. Compl. Ex. B at 38-46)	Distributor	Mar. 6, 2023	Black Berkey Filters Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters

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<sup>16</sup> Vendor B, a third-party manufacturer, was issued a SSURO on February 3, 2023. Am. Compl. Ex. B at 25-28. It was not limited to Berkey products. Vendor B modified its website and labels to comply with FIFRA, so EPA terminated the SSURO. Because the SSURO to Vendor B was terminated, there are no justiciable claims pertaining to Vendor B. *See Chevron U.S.A., Inc. v. Traillour Oil Co.*, 987 F.2d 1138, 1153 (5th Cir. 1993); *see also Powell v. McCormack*, 395 U.S. 486, 496 (1969) (A controversy is moot when there are no “live issues” or “the parties lack a legally cognizable interest in the outcome.”).

			Crown Berkey Water Filters Berkey Light Water Filters
Mountain Mama Natural Foods, Inc  (Am. Compl. Ex. B at 47-53)	Distributor	Mar. 7, 2023	Black Berkey Filters Big Berkey Water Filters
Good Earth Natural Foods Company,  (Am. Compl. Ex. B at 54-61)	Distributor	May 2, 2023	Black Berkey Filters Travel Berkey Water Filters Big Berkey Water Filters Royal Berkey Water Filters Imperial Berkey Water Filters Crown Berkey Water Filters
Berkey International LLC,  (Am. Compl. Ex. B at 62-69)	Manufacturer	May 8, 2023	Black Berkey Filters Travel Berkey Water Filters, Big Berkey Water Filters, Royal Berkey Water Filters, Imperial Berkey Water Filters, Crown Berkey Water Filters

To date, the above violative products still contain silver, are being advertised for pesticidal purposes, and are not registered with EPA as pesticides or pesticidal products.<sup>17</sup>

#### **D. Procedural History**

On August 9, 2023, Plaintiffs filed a Complaint and an Application for Temporary Restraining Order, and Preliminary, and Permanent Injunctions against EPA. ECF No. 1. The Complaint alleged that EPA violated the Administrative Procedure Act (“APA”) by exercising its pesticide enforcement mandate under FIFRA. *Id.* Further, Plaintiffs alleged that SSUROs issued

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<sup>17</sup> *What does Berkey Water Filter Remove? Lab Test Results*, App. at 1-39; available at [https://theberkey.com/pages/test-result?\\_pos=1&\\_sid=512c81191&\\_ss=r](https://theberkey.com/pages/test-result?_pos=1&_sid=512c81191&_ss=r) (last viewed on August 29, 2023) (“The Berkey filters can be classified as water purifiers because they remove 99.999999% of pathogenic bacteria and 99.999% of viruses, significantly exceeding the standard.”)

to the third-party distributors and manufacturers have caused irreparable harm to Plaintiffs such that injunctive relief is warranted. *Id.*

On August 10, 2023, this Court denied Plaintiffs' request for a temporary restraining order noting "TROs are extraordinary relief and rarely issued" and set an expedited briefing schedule for Plaintiffs' Application for Preliminary Injunction. ECF No. 6 (internal citation omitted). On August 17, 2023, EPA, its Administrator, and other Defendants sued in their official capacities filed a Response in Opposition to Plaintiffs' Motion for Preliminary Injunction. ECF Nos. 9-12. On August 24, 2023, in reply, Plaintiffs filed an Amended Complaint with an Amended Motion for Preliminary and Permanent Injunction,<sup>18</sup> an additional Declaration from James B. Shepherd with exhibits, and a Reply in Support of the First Motion for Preliminary Injunction.<sup>19</sup> ECF Nos. 13-15. On August 28, 2023, the Court denied Plaintiffs' First Motion for Preliminary Injunction as moot "[b]ecause the First Amended Complaint does not refer to or incorporate prior pleadings and attempts to rectify issues identified in the First Motion for Preliminary Injunction." ECF No. 16. The Court also set a new expedited briefing schedule for the "Amended Preliminary Injunction (ECF No. 14)." *Id.*

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<sup>18</sup> The Amended Complaint contains a plethora of allegations that EPA violated many of Plaintiffs' constitutional rights as well as numerous allegations of APA violations. This opposition brief is intended to address the allegations contained within Plaintiffs' Amended Motion for Preliminary Injunction and to demonstrate why injunctive relief is inappropriate. EPA reserves the right to assert all defenses afforded in the Federal Rules of Civil Procedure, including but not limited to those available under Rule 12(b).

<sup>19</sup> The Amended Complaint and Plaintiffs' Reply in Support of the First Motion for Preliminary Injunction state Plaintiffs have removed their "individual capacity claims" against EPA personnel and that EPA personnel are now only being sued in their "official capacities." Am. Compl. ¶ 6; ECF No. 15 ¶ 25 (section iii).

## Legal Standards

### A. Preliminary Injunction Standard

The Fifth Circuit has repeatedly cautioned “that a preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements.” *Bluefield Water Ass’n, Inc. v. City of Starkville*, 577 F.3d 250, 253 (5th Cir. 2009) (internal quotation marks omitted). Specifically, the moving party must demonstrate that (1) “he is likely to succeed on the merits”; (2) “he is likely to suffer irreparable harm in the absence of preliminary relief”; (3) “the balance of equities tips in his favor”; and (4) “an injunction is in the public interest.” *Winter*, 555 U.S. 7, 20 (2008). *Winter* requires a plaintiff to show more than a mere “possibility” of harm; instead, the movant must prove that there is a “likelihood” of irreparable injury in the absence of an injunction. *Id.* at 21-22.

### B. Merits Issues

This Court has jurisdiction under FIFRA to review “final actions” of the EPA Administrator other than those actions issued “following a public hearing.” 7 U.S.C. § 136n(a), (b). “Where,” as with FIFRA, “a federal statute providing for judicial review of an agency’s action does not itself provide a standard of review, the general standard of review of agency action established in the [APA] applies.” *Ellis v. Housenger*, 252 F. Supp. 3d 800, 808 (N.D. Cal. 2017) (internal quotation marks omitted).<sup>20</sup>

Under that standard, the party challenging an agency action must show that the action was “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C.

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<sup>20</sup> Plaintiffs invoke FIFRA’s judicial review provision (Am. Compl. ¶ 13) but plead their claims under the APA. This is incorrect. The APA provides a cause of action only when there is “no other adequate remedy” available. 5 U.S.C. § 704. Because FIFRA affords an appropriate party with the opportunity to seek judicial review of EPA’s SSUROs, the APA does not.

§ 706(2)(A); *ExxonMobil Pipeline Co. v. U.S. Dep’t of Trasp.*, 867 F.3d 564, 571 (5th Cir. 2017). The court’s review is limited to the administrative record compiled by the agency. *Fed. Power Comm’n v. Transcon. Gas Pipe Line Corp.*, 423 U.S. 326, 331 (1976). The arbitrary or capricious standard of review is deferential and narrow, and a court may not substitute its judgment for that of the agency. *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The court asks only “whether the [agency’s] decision was based on a consideration of the relevant factors” and “whether [the agency] has [made] a clear error in judgment.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977). Particular deference is given to an agency regarding technical matters in its area of expertise. *Balt. Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983).

### **Argument and Authorities**

#### **A. Plaintiffs are Unlikely to Succeed on the Merits.**

To demonstrate entitlement to the extraordinary remedy of a preliminary injunction, Plaintiffs must establish that they are likely to succeed on the merits. Plaintiffs have wholly failed to meet this burden; their motion must therefore be denied.

As a threshold matter, Plaintiffs must show they likely have standing to assert the claims in this lawsuit. *Speech First, Inc. v. Fenves*, 979 F.3d 319, 330 (5th Cir. 2020), as revised (Oct. 30, 2020) (collecting cases). More specifically, Plaintiffs must show it is probable that they suffered an injury that is (1) “concrete, and particularized, [and] actual or imminent”; (2) “fairly trace[able] to the challenged action, and not . . . th[e] result [of] the independent action of some third party not before the court”; and (3) “it must be likely as opposed to merely speculative that the injury will be redressed by a favorable decision.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (internal quotation marks omitted); ECF No. 15 ¶ 3; see also *Speech First*, 979 F.3d at 330.

The burden rests with Plaintiffs to prove this indispensable part of their case. *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990).

Here Plaintiffs, none of whom is Berkey International, rely on alleged injuries suffered by Berkey International and other third-party vendors after these entities were issued SSUROs, as well as claims that Plaintiffs have lost royalties and market share and that the reputation of NMCL and the Berkey brand has suffered. Am. Compl. ¶¶ 89-92; Am. Mot. ¶¶ 177, 186-193, 197; ECF No. 15 ¶¶ 1, 6, 27. Plaintiffs invite this court to view royalties, market share, and reputation as earned entitlements with an objective value that is immune to market conditions. Am. Compl. ¶¶ 89-92; Am. Mot. ¶¶ 186-193; ECF No. 15 ¶¶ 1, 4-6. To the contrary, the value of all these things is highly variable, and Plaintiffs' claims of loss are speculative at best. Plaintiffs also claim their purported injuries are traceable to EPA's issuance of SSUROs and that a favorable decision in this case would redress those injuries. There is a serious question about whether Plaintiffs have provided sufficient evidence in support of these claims, and their alleged injuries, even if proven, do not rise to the level of irreparable harm. *See infra* pp. 21-28. But Defendants will assume for the purposes of this motion only that Plaintiffs may have Article III standing.<sup>21</sup>

### **1. Plaintiffs have failed to demonstrate third-party standing.**

Even assuming their Article III standing, Plaintiffs have no third-party standing to bring suit to challenge SSUROs issued to other entities. *See Ward v. Santa Fe Indep. Sch. Dist.*, 393 F.3d 599, 606 (5th Cir. 2004) (A plaintiff typically "must assert his or her own legal rights and interests and cannot rest a claim to relief on the legal rights or interests of third parties.") (citing *Warth v. Seldin*, 422 U.S. 490, 499 (1975)); *see also Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004)

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<sup>21</sup> Defendants reserve the right to address Article III standing more fully at a later stage of these proceedings.

(assuming a litigant's Article III standing but dismissing their claims for lack of third-party standing). "Federal courts must hesitate before resolving a controversy, even one within their constitutional power to resolve, on the basis of the rights of third persons not parties to the litigation." *Singleton v. Wulff*, 428 U.S. 106, 113 (1976). This is so for two reasons: "First, the courts should not adjudicate such rights unnecessarily, and it may be that in fact the holders of those rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not." *Id.* at 113-114. "Second, third parties themselves usually will be the best proponents of their own rights." *Id.* at 114. The prudential rule against third-party standing is subject to limited exception, but only "where 'the party asserting the right has a 'close' relationship with the person who possesses the right' and 'there is a 'hindrance' to the possessor's ability to protect his own interests.'" *Vote.Org v. Callanen*, 39 F.4th 297, 303-04 (5th Cir. 2022) (quoting *Kowalski*, 543 U.S. at 130).

The final actions at issue are SSUROs that EPA issued to third parties, not to Plaintiffs. The SSURO recipients have not sought judicial review of EPA's actions. And if Plaintiffs wish to do so, they must show both that they have a sufficiently close relationship with the SSURO recipients and that those parties cannot vindicate their own rights. Plaintiffs have not acknowledged, let alone carried, their burden.

*Pizza Hut, LLC v. Ronak Foods, LLC*, No. 5:21-CV-00089-RWS, 2022 WL 3544403, at \*11-\*12 (E.D. Tex. June 17, 2022), cited by Plaintiffs, ECF No. 15 ¶¶ 4-5, does nothing to alter this conclusion. In that breach-of-contract case, a franchisor (Pizza Hut) was contractually entitled to "Advertising Fees" from its franchisees. Under the contracts at issue, the franchisees were also obliged to pay membership dues to a third-party franchise holders' association. Because those membership dues were "credited, dollar for dollar towards their obligation to pay the Advertising

Fees to Pizza Hut,” the franchisees’ failure to pay membership dues amounted to a failure to pay Pizza Hut an equivalent amount in advertising fees, which Pizza Hut could recover through damages. *Pizza Hut, LLC*, 2022 WL 3544403, at \*12 (internal quotation marks omitted). *Pizza Hut* thus stands for the unremarkable proposition that a party can sue to collect money owed under a contract. *Pizza Hut* assuredly did not hold that a corporate entity may sue to challenge an enforcement action against anyone with whom it does business; indeed, we are aware of no case that does.

Plaintiffs’ evident lack of third-party standing means that their claims are nonjusticiable and they are unlikely to prevail on the merits.

**2. Even if they are justiciable, Plaintiffs’ claims fail on the merits.**

**a. EPA had reason to believe that Berkey products were unregistered pesticides.**

EPA may issue SSUROs whenever it has “reason to believe” the recipient has distributed or sold, or intends to distribute or sell, a pesticide or device “in violation of any” provision of FIFRA. 7 U.S.C. § 136k(a). The crux of Plaintiffs’ latest merits argument is that EPA had no reason to believe that Berkey products were “intended” for a pesticidal purpose and thus had no grounds to issue SSUROs directed at those products. *See, e.g.*, Am. Compl. ¶¶ 58, 125, 151; Am. Mot. ¶¶ 174-85. These assertions do not withstand scrutiny.

Under EPA regulations—that Plaintiffs fail to acknowledge but that have been in place since 1988—a “pesticidal purpose” means “use for the purpose of preventing, destroying, repelling, or mitigating any pest.” 40 C.F.R. § 152.15; *see also* Pesticide Registration Procedures; Pesticide Data Requirements, 53 Fed. Reg. 15952 (May 4, 1988). And a “substance is considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration,” if, among other things:

(a) The person who distributes or sells the substance claims, states, or implies (by labeling or otherwise):

(1) That the substance (either by itself or in combination with any other substance) can or should be used as a pesticide; or

...

(b) The substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than

(1) use for pesticidal purpose (by itself or in combination with any other substance)[; or]

...

(c) The person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

40 C.F.R. § 152.15.

Berkey products were marketed with claims that they “prevent[ed], destroy[ed], or mitigate[ed],” *id.*, viruses and pathogenic bacteria, and they contain antimicrobial silver, a pesticide registered for use on water filters for the pesticidal purpose of eliminating microbes that can grow on the filter, *see supra* p.7. EPA therefore had “reason to believe”—as required for the issuance of a SSURO under 7 U.S.C. § 136k(a)—that Berkey products were pesticides intended for a pesticidal purpose. And because Berkey products are marketed with public health claims about their purported ability to purify water, EPA also had reason to believe that those products fell outside the treated article exemption from otherwise applicable registration requirements. Finally, because Berkey products are not registered under FIFRA, EPA had reason to believe that their continued sale violated FIFRA’s bar on the sale of unregistered pesticides.

None of this entailed the issuance of a “new rule” and Plaintiffs’ assertions to the contrary, Am. Compl. ¶¶ 113-18, are baseless. Nor did EPA’s issuance of the SSUROs reflect any change in position. The regulations cited above have been in place 35 years. And for decades, EPA has

warned: (1) that devices, including water filters, that incorporate pesticides are pesticides under FIFRA; and (2) that as a general rule, the treated article exemption from otherwise applicable pesticide registration requirements does not apply to products that make broad public health claims. *See supra* pp. 4-6. Against this backdrop, Plaintiffs' self-serving complaints about "unfair surprise" (Am. Compl. ¶¶ 97-112) ring hollow.

**b. Plaintiffs' other statutory and constitutional claims lack merit.**

Plaintiffs also assert that EPA impermissibly legislated (in violation of the nondelegation doctrine), and failed to faithfully execute the laws, by "more broadly defin[ing] 'pesticide' to exceed the limits of its congressionally established authority." Am. Compl. ¶ 140. Not so. FIFRA defines "pesticide" to include "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest," 7 U.S.C. § 136(u), a definition that easily encompasses Berkey products. Plaintiffs object to this straight-forward application of statutory text. And while they never clearly state the basis of their objection, they appear to argue based on ambiguous and selectively quoted legislative history that a pesticide ceases to be a pesticide when it is incorporated in a product. Am. Compl. ¶¶ 152-55. But Plaintiffs identify no textual basis for their claim. And "legislative history is not the law." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1814 (2019). Plaintiffs have therefore failed to demonstrate that they are likely to succeed on the merits of the claim contained in count four of the Amended Complaint.

While the Court need go no further, Plaintiffs' invocation of the nondelegation doctrine and the Take Care Clause are unlikely to succeed for other reasons as well. "The nondelegation doctrine bars Congress from transferring its legislative power to another branch of Government." *Gundy v. United States*, 139 S. Ct. 2116, 2121 (2019) (plurality). The prohibition runs to Congress, not to agencies. *See Whitman v. Am. Trucking Ass 'ns*, 531 U.S. 457, 472 (2001) ("In a delegation

challenge, the constitutional question is whether the statute has delegated legislative power to the agency.”). By arguing that EPA violated the nondelegation doctrine by significantly expanding the scope of its delegated authority, Plaintiffs get things exactly backwards. *See Am. Compl.* ¶ 141 (arguing that “FIFRA may have been constitutionally sound until this last year,” but EPA’s allegedly “arbitrary reinterpretation” of the term “pesticide” rendered the statute unconstitutional). They fare no better by insisting that the statutory definition of “pesticide” lacks any intelligible principle because Congress set no “boundaries” on what constitutes a “‘substance or mixture of substances’” under FIFRA. Am. Compl. ¶ 140. In fact, a substance or mixture of substances is a pesticide under FIFRA only when it is “intended for preventing, destroying, repelling, or mitigating any pest.” 7 U.S.C. § 136(u). Plaintiffs simply ignore the intelligible principle that that Congress provided.

Plaintiffs’ reliance on the Take Care Clause is similarly misplaced. The Supreme Court has long “distinguished between claims of constitutional violations and claims that an official has acted in excess of his statutory authority,” *Dalton v. Specter*, 511 U.S. 462, 472 (1994), and the latter “are not ‘constitutional’ claims,” *id.* at 473. Plaintiffs’ passing reference to the Take Care Clause cannot transform what is, at bottom, an argument about the meaning of 7 U.S.C. § 136(u), into a dispute of constitutional dimensions.

Plaintiffs are no more likely to succeed under the Fifth Amendment’s Due Process Clause. For one thing, their procedural due process arguments merely rehash their earlier claims about EPA’s alleged failure to follow notice and comment procedures before issuing a new rule or reversing its prior position. See Am. Compl. ¶¶ 156-64. Those claims rest on faulty premises; EPA’s actions were based on long-standing regulations and guidance and entailed no change in position. *See supra* pp. 17-18. Moreover, Plaintiffs never clearly define the constitutionally

protected property or liberty interests that give rise to their due process claim. *See Kovac v. Wray*, 363 F. Supp. 3d 721, 756 (N.D. Tex. 2019) (“As a threshold issue . . . the government action complained of must ‘deprive individuals of “liberty” or “property” interests within the meaning of the Due Process Clause of the Fifth . . . Amendment.’” (quoting *Mathews v. Eldridge*, 424 U.S. 319, 332 (1976)) (second alteration in original). The only injuries Plaintiffs claim to have suffered are reputational harms and some measure of lost revenue. Am. Compl. ¶¶ 158-59. But “reputation alone, apart from some more tangible interests such as employment, is [n]either ‘liberty’ [n]or ‘property’ by itself sufficient to invoke the procedural protection of the Due Process Clause.” *Paul v. Davis*, 424 U.S. 693, 701 (1976). And the Fifth Circuit has cautioned in the qualified immunity context that there is no “clearly established” “property interest in . . . lost profits.” *Doss v. Morris*, 642 F. App’x 443, 447 (5th Cir. 2016). Finally, even setting all this aside, EPA has not issued a SSURO to Plaintiffs, and Plaintiffs cite no authority for the proposition that the United States is constitutionally compelled to afford “notice or an opportunity to be heard,” Am. Compl. ¶ 160, to every entity claiming a business relationship with the target of a government enforcement action. Plaintiffs are thus unlikely to prevail on their Due Process Clause claim.

So too for their claim under the Ninth and 10th Amendments, which they read to “protect[] from government interference” “every water filter that uses a gravity-fed element comprising a porous medium to capture contaminants.” Am. Compl. ¶ 169. This argument is unmoored from the Constitution’s text or precedent. No such right exists.

**B. Plaintiffs have Failed to Demonstrate That They Are Likely to Suffer Irreparable Harm in the Absence of an Injunction.**

Plaintiffs bear the burden of proving, not just alleging, that, unless an injunction issues, they will suffer actual harm that is “both certain and great[.]” *Navistar, Inc. v. U.S. Env’t Prot. Agency*, No. 11-cv-449 (RLW), 2011 WL 3743732, at \*\*2-3 (D.D.C. Aug. 25, 2011) (internal

quotation omitted). As part of their burden of proof, Plaintiffs “must demonstrate a causal connection between the alleged harm and the actions to be enjoined[.]” *Id.*, 2011 WL 3743732, at \*2 (internal quotation omitted); *see also Direct Biologics, LLC v. Kimera Labs, Inc.*, No. 4:18CV2039 HEA, 2019 WL 4141019, at \*3 (E.D. Mo. Aug. 30, 2019).

Plaintiffs make a general assertion that because an SSURO instructs the recipient not to sell products subject to the order, its issuance causes irreparable harm because it “stop[s] business.” ECF No. 15 ¶ 29. If this were correct then every recipient of an SSURO who believed it was issued in error, and, indeed, anyone who does business with a recipient, would have an almost automatic right to a preliminary injunction while its challenge was decided. This is inconsistent with FIFRA’s regulatory scheme, which allows EPA to stop the sale of potentially dangerous products so long as EPA has reason to believe they are being sold in violation of FIFRA. Further, as explained below, economic loss is not irreparable harm absent evidence of a risk to the very existence of the business of the party seeking an injunction. No such demonstration has been made here.

Plaintiffs’ specific claims of irreparable harm can be grouped into four categories:

- A claim that the JBS Trust will lose royalties. Am. Mot. ¶¶ 186, 193.<sup>22</sup>
- Claims that non-party licensees have been injured. Am. Mot. ¶¶ 189-191.
- Claims of lost sales and loss of market share. Am. Mot. ¶¶ 187-188, 194-195, 201.
- Unsupported claims of other business injuries, such as loss of reputation and business opportunities. Am. Mot. ¶ 201.

Plaintiffs also make a number of vague, passing claims of harm, such as their assertion that the SSUROs “have left NMCL in a state of confusion.” Am. Mot. ¶ 199; *see also id.* ¶¶ 196-198, 200.

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<sup>22</sup> Plaintiffs allege that NMCL has lost royalties, Am. Compl. ¶ 90, but do not assert any future loss will constitute irreparable harm.

Although Plaintiffs have added new allegations of harm, they have still failed to demonstrate that *irreparable* harm will result to any of them unless an injunction is granted.

**1. The JBS Trust's alleged lost royalties are not irreparable harm.**

Plaintiffs claim the JBS Trust will be irreparably harmed by the loss of royalty payments during the pendency of this lawsuit. Specifically, non-party Berkey International is contractually obligated under a license agreement to pay a royalty on the sales of Berkey products to NMCL, which, in turn, is obligated under another license agreement to pay royalties to the JBS Trust. Am. Compl. ¶¶ 32; Am. Mot. ¶¶ 186, 193; ECF No. 15 ¶ 26. Claims for economic loss, however, are insufficient to establish irreparable harm absent evidence that, without a temporary injunction, the very existence of the JBS Trust's business is threatened while the lawsuit is pending. *See Digit. Generation, Inc. v. Boring*, 869 F. Supp. 2d 761, 781 (N.D. Tex. 2012). This is true even if alleged financial losses will not be recoverable. *See Biovail Corp. v. FDA*, 519 F. Supp. 2d 39, 49 (D.D.C. 2007). Here, Plaintiffs do not allege that lost royalties will drive the JBS Trust out of business or that all royalty payments have ceased. Berkey products are still being offered for sale by numerous sellers on Amazon and elsewhere.<sup>23</sup> Indeed, some of the retailers that received SSUROs are still advertising Berkey products for sale on their own websites.<sup>24</sup> Plaintiffs have submitted no evidence of the amount of royalties received by the JBS Trust. It is not possible to compare royalties before and after the issuance of the SSUROs or to compare the lost royalties with the total amount of royalties received. Without such evidence, it cannot be concluded that any lost

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<sup>23</sup> See [Big Berkey Gravity-Fed Water Filter System 2.25 Gallon with 2 Black Berkey Elements, 2 Berkey PF-2 Fluoride and Arsenic Reduction Elements](#), Amazon.com (last visited Aug. 17, 2023).

<sup>24</sup> See Fitz Wellness Center, *Berkey Purification Systems*, Clean Water, <https://www.fritzwellness.com/water> (last visited Aug. 17, 2023); Eden Valley Family Farms, *Big Berkey Water Filter*, <https://edenvalleyfood.com/product/big-berkey-water-filter/> (last visited Aug. 17, 2023).

royalties threaten to drive the trust out of business during the pendency of this lawsuit. Accordingly, Plaintiffs' claim of lost royalties is insufficient to establish irreparable harm.

**2. Plaintiffs cannot establish irreparable harm based on alleged injuries to their licensees or other nonparties.**

In addition to the JBS Trust's lost royalties, Plaintiffs allege specific injuries to Berkey International, Am. Mot. ¶¶ 189-191, a licensee of NMCL, and claim that an unidentified vendor of Berkey International was forced to lay off skilled workers. Am. Mot. ¶ 190. Plaintiffs also speculate that consumers may be harmed by using "knock off" filters. Am. Mot. ¶ 192.

Plaintiffs cannot, however, establish irreparable harm to themselves based on alleged injuries to non-parties. *See Winter*, 555 U.S. at 20 ("A plaintiff seeking a preliminary injunction must establish that *he* is likely . . . to suffer irreparable harm in the absence of preliminary relief") (emphasis added); *see also Morice v. Hosp. Serv. Dist. # 3*, No. 18-7945, 2019 WL 1517954, at \*7 (E.D. La. Apr. 8, 2019) ("Dr. Morice lacks standing to seek injunctive relief for harm that will occur to others, even to others who would allegedly benefit from such injunctive relief"); *Smith v. Okolona Mun. Separate Sch. Dist.*, No. CIV. A. 1:97cv226-D-, 1997 WL 560922, at \*2 (N.D. Miss. July 31, 1997) ("It is some showing of 'irreparable harm' to Dr. Smith that must be demonstrated to this court, and not to third persons not parties to this lawsuit.").

**3. Plaintiffs' claims of lost sales and market share are insufficient to establish irreparable harm.**

Plaintiffs make numerous hyperbolic, unsupported claims of lost sales and loss of market share. Am. Mot. ¶¶ 192, 201. There is no evidence, however, that Plaintiffs themselves have lost direct sales of Berkey products. They are complaining about injuries to non-party licensees. As to Plaintiffs, loss of sales and market share are relevant only to the claim that the JBS Trust will lose royalty payments, and as discussed above that claim fails to establish irreparable harm.

Additionally and separately, without evidence, claims of lost sales and lost market share

cannot establish irreparable harm. *See Pruvit Ventures, Inc. v. Forevergreen Int'l LLC*, No. 4:15-CV-571-ALM-CAN, 2015 WL 9876952, at \*3 (E.D. Tex. Dec. 23, 2015). Plaintiffs only offer evidence to support their claim that the issuance of the SSUROs has caused a decline in sales on Amazon in 2023. Plaintiffs' evidence, however, is meager and insufficient.

First, there is no evidence that Plaintiffs, Berkey International, any other party to one of the license agreements, or any of the other entities that received SSUROs sell Berkey products on Amazon. It is entirely speculative to infer a causal connection between (1) non-parties and non-SSURO recipients allegedly losing sales on Amazon and (2) royalties paid to the JBS Trust allegedly decreasing. And to the extent that such a connection can be inferred—by assuming that these other sellers were licensed by NMCL, that some portion of their sales flow to NMCL and thence to the JBS Trust, and thus that any drop in their sales affects the trust—it remains merely an inference. Plaintiffs have offered no hard evidence to move this attenuated chain of alleged losses from the realm of assumption and speculation to fact.

Second, Plaintiffs' evidence fails to demonstrate that any loss of Amazon sales can be traced to the SSUROs. For example, Plaintiffs allege that

in February of 2023, NMCL's flagship Big Berkey system alone was clearly the market leader with sales on Amazon approximately 2.5 times that of the closest competitor. Since then, sales have suffered a decrease in sales [sic] of approximately 90%. Big Berkey systems have fallen below two competitors, which are now selling nearly three times the volume that Big Berkey systems are selling.

Am. Mot. ¶ 187.

These allegations are misleading. The first SSURO was issued in December 2022. Plaintiffs' Exhibit B-17 (ECF No. 1-2 at 222) shows that, in January 2023, sales of the Big Berkey were at the same level as during the first six months of 2022. In February 2023, sales of the Big Berkey spiked and were 2.5 times *higher* than at any time during the first half of 2022. Since then, sales have declined but were still at 2022 levels in May 2023. Moreover, sales of competitors did

not markedly increase as sales of the Big Berkey declined; they stayed the same. This does not support the conclusion that, because of the SSUROs, consumers stopped buying the Big Berkey and started buying more of its competitors' products.

Additionally, there are more likely causes than the SSUROs for any decline in Amazon sales. For example, a Google search for “Berkey” or “Berkey Waters filter” returns nothing about the SSUROs but returns, within the first few results, a July 2022 New York Times’ Wirecutter article expressly criticizing and declining to recommend the “Big Berkey”. Tim Hefferman, *The Big Berkey Water Filter: Uncertified and Inconvenient*, N.Y. TIMES WIRECUTTER (July 22, 2022), App. 40-63, available at <https://www.nytimes.com/wirecutter/reviews/big-berkey-water-filter-system/>. The same search generates suggested searches for “berkey water filter lawsuit” and “why are berkey water filters banned in california”.<sup>25</sup> “Berkey water filter lawsuit” returns references to the pending class action lawsuit against NMCL,<sup>26</sup> in which the plaintiffs claim Berkey products do not work as advertised. Likewise, “why are berkey water filters banned in california” returns numerous references to the fact that Berkey water filters cannot be sold in California because they are not NMF/ANSI certified (a third party certification that they comply with National Standards

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<sup>25</sup> The Google search engine is inherently dynamic, and the same search terms may return different results depending on a number of factors including the location where the search is performed, the searcher’s previous searches, and changes to Google’s algorithm. See Sabina Plimmer, [Why Do I Get Different Google Results in Different Locations?](#) (last visited Aug. 15, 2023). However, searches in August 2023 performed in Washington, DC; Long Island, New York; and Dallas, Texas, using the terms discussed herein all returned the results discussed.

<sup>26</sup> See, e.g., u/Ecstatic-Fun-2390, Do not order from berkeywaterfilter.com, r/Berkey, [https://www.reddit.com/r/Berkey/comments/zmu6e1/do\\_not\\_order\\_from\\_berkeywaterfiltercom/](https://www.reddit.com/r/Berkey/comments/zmu6e1/do_not_order_from_berkeywaterfiltercom/) (last visited Aug. 17, 2023).

for Water Treatment Systems).<sup>27</sup> A consumer could easily come away with the impression that Berkey filters are in fact banned in California, even though Plaintiffs dispute that characterization.

All of these—the New York Times’ negative review, the class action lawsuit, and the perception that California has banned Berkey water filters—have far greater public visibility on the Internet than the SSUROs. Indeed, even a targeted search for “Berkey SSURO” returns links to the SSURO issued to Berkey International<sup>28</sup> and to a listing on EPA’s website about the SSURO issued to James Enterprises, but not the other SSUROs. And this listing provides no details other than that the SSURO was issued and that the matter is on EPA’s enforcement docket.<sup>29</sup> This search returns little else about the SSUROs except for references posted by Plaintiffs and their counsel. Therefore, it cannot be assumed that any loss of sales on Amazon (or elsewhere) is necessarily attributable to the SSUROs.

Finally, Plaintiffs assert that Berkey products have not just lost sales and market share but lost them to competitors. Am. Mot. ¶ 194. Courts are reluctant to find that claims of competitive loss in the marketplace constitute irreparable harm, especially where, as here, Plaintiffs have failed to explain why they could not regain these competitive losses if they prevail or if they lose and the law is subsequently complied with. *See Astellas Pharma US, Inc. v. FDA*, 642 F. Supp. 2d 10, 22-23 (D.D.C. 2009); *Biovail*, 519 F. Supp. 2d at 48-49.

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<sup>27</sup> See Eva Hagen, [Here’s Why Berkey Water Filters Are Banned in California](#), greenmatters (July 12, 2023 9:42 A.M. ET), (last visited August 16, 2023); SR, Berkey Class Action Lawsuit, [Comment to Travel Berkey Gravity-Fed Water Filter with 2 Black Berkey Elements](#) (Aug. 4, 2023) (last visited Aug. 14, 2023).

<sup>28</sup> <https://eaudoulton.com/wp-content/uploads/2023/05/FIFRA-08-2023-0038-SSURO-BerkeyInternational-2023.pdf>

<sup>29</sup> <https://yosemite.epa.gov/oa/rhc/epaadmin.nsf/Filings/A56B5681D18012EF85258925007F0A58?OpenDocument>

**4. Plaintiffs' general, unsupported claims of loss of reputation and goodwill do not establish irreparable harm.**

Plaintiffs allege harm to reputation, harm to the Berkey brand, and loss of goodwill but provide no specifics and no supporting evidence.<sup>30</sup> Am Mot. ¶¶ 197, 205. Courts are often and rightfully reluctant to accept claims of reputational damage, agreeing that the harm is sufficiently irreparable only when it is “pervasive and certain to occur.” *Tex. Marine & Brokerage, Inc. v. Bennington Marine, LLC*, No. 1:12-CV-397, 2012 WL 12888827, at \*5 (E.D. Tex. Oct. 17, 2012), *report and recommendation adopted*, No. 1:12-CV-397, 2012 WL 12892168 (E.D. Tex. Nov. 9, 2012); *see also Andritz Sundwig GmbH v. United States*, No. 4:18-2061, 2018 WL 3218006, at \*11 (S.D. Tex. July 2, 2018) (finding speculation about reputational injury insufficient to prove irreparable harm). Here, Plaintiffs have offered no evidence that harm to reputation, brand, or goodwill is likely to occur or that, if it does, it will not be due to the New York Times negative review, the class action lawsuit, or the perception that Berkey products are banned in California, all of which have a higher public profile than the SSUROs.

**5. None of Plaintiffs' other claims of irreparable harm is sufficient.**

Finally, Plaintiffs make additional claims of harm that are difficult to categorize. For example, Plaintiffs allege that EPA agents have refused to approve new websites for James Enterprises and NMCL, that EPA has not “informed them specifically of what they can and cannot say,” and that EPA “Region 8 has stated that NMCL is making pesticide statements” in the class action lawsuit. Am. Mot. ¶ 196. Additionally, the SSUROs have allegedly “left NMCL in a state of confusion.” Am. Mot. ¶ 199. And EPA has allegedly “indicated” to some unidentified person that it will not allow the “Berkey trademark” to be used with third-party ceramic filters that can be

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<sup>30</sup> ECF No. 1-2 at 210-213 contains email traffic about statements allegedly made in France that were critical of Berkey products. There is no mention of the SSUROs, however.

used in Berkey products. Am. Mot. ¶ 198. Even assuming these vague allegations are accurate, which is disputed, Plaintiffs have not shown they will cause irreparable harm while this lawsuit is pending.

**C. The Balance of the Equities and the Public Interest Weigh Against an Injunction.**

Plaintiffs bear the burden of proof as to all the elements required for a preliminary injunction. *See Kern River Gas Transmission Co. v. Coastal Corp.*, 899 F.2d 1458, 1462 (5th Cir. 1990). Because Plaintiffs cannot demonstrate irreparable harm, their Motion can be denied without further inquiry. The Court need not consider anything else. *See Harris v. United States*, 745 F.2d 535, 536 (8th Cir. 1984). However, the other factors—the balance of equities and the public interest—also favor denial of injunctive relief.

Where, as here, the opposing party is the government, the balance of equities and the public interest are merged into a single inquiry. *See Nken v. Holder*, 556 U.S. 418, 435 (2009). Plaintiffs cite two public interest factors that they claim support temporary equitable relief: (1) EPA’s alleged change in its position as to whether registration is required for Berkey products; and (2) the claim that, if Berkey products cannot be purchased, consumers will be forced to rely on inferior imitations. Am. Mot. ¶¶ 208-210. Neither of these supports injunctive relief.

As discussed above, Berkey products use silver as an antimicrobial, and the ingestion of silver can cause health problems in humans and animals. Silver has been regulated as an anti-microbial pesticide for almost 70 years, and water filter manufacturers that use silver to inhibit the growth of bacteria and other microbes have registered their water filters as pesticides with EPA.

Thus, EPA has not changed its position, and, when EPA discovered that Berkey products contain silver and were being marketed with broad public health claims, it acted consistently with its long-standing policy. Given the harm that can be caused by the ingestion of silver, and the fact

that other manufacturers have registered their silver-containing water filters, the public interest does not favor allowing anyone to continue to sell Berkey's unregistered products. That Plaintiffs' licensees had sold Berkey products for some time in violation of the law is irrelevant. There is no estoppel against the government whereby if one violates the law for a certain period without detection, or even with acquiescence, an enforcement action cannot later be brought. *See Utah Power & Light v. United States*, 243 U.S. 389, 408-09 (1917).

Additionally, consumers have other alternatives besides imitations of Berkey filters. For example, as noted in the New York Times article discussed above, there are pitcher and under-the-sink water filters that are NMF/ANSI certified (which Berkey products are not) and are smaller, cheaper, and easier to maintain.

Thus, Plaintiffs have failed to demonstrate that the public interest favors a preliminary injunction.

### **Conclusion**

For the reasons set forth above, Plaintiffs' amended motion for a preliminary injunction should be denied.

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Certificate of Service

On August 31, 2023, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ *Mark L. Walters*

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